AO 91 (Rev. 11/11) Criminal Complaint

CLERK'S OFFICE U.S. DIST. COURT
AT ABINGDON, VA
FILED

SEP 26 2018

JULIA C. DUDLEY, CLERK
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UNITED STATES DISTRICT COURT

for the

Western District of Virginia

United States of America
v.
Bryan Lewis

Case No. 1:18mj157

Defendant(s)

CRIMINAL COMPLAINT

I, the complainant in this case, state that the following is true to the best of my knowledge and belief.

On or about the date(s) of Aug 1, 2017 to Jan 8, 2018 in the county of Roanoke in the Western District of Virginia, the defendant(s) violated:

Code Section	*Offense Description*
18 USC § 1365	Tampering with a Drug

This criminal complaint is based on these facts:

See Attached Affidavit

☑ Continued on the attached sheet.

Complainant's signature

Darren Petri, Special Agent

Printed name and title

Sworn to before me and signed in my presence.

Date: 9/26/18

Judge's signature

City and state: Abingdon, VA

Pamela Sargent, U.S. Magistrate Judge

Printed name and title

AFFIDAVIT

I, Darren Petri, Special Agent for the Food and Drug Administration, Office of Criminal Investigation ("FDA/OCI"), being duly sworn, depose and state as follows:

I am a Special Agent with the FDA/OCI, assigned to the Washington Metro Field Office. Prior to my current assignment, I was employed by the Department of Veterans Affairs, Office of Inspector General, Criminal Investigation Division, assigned to the Washington Field Office, Washington, D.C. I worked there from April 2006 to February 2013. Previously, I was employed by the FDA/OCI and worked there from March 2004 to April 2006. Prior to my employment with the FDA/OCI, I worked for the United States Army Criminal Investigation Command ("USACIDC"), Major Procurement Fraud Unit, Ft. Belvoir, Virginia, from September 2002 to March 2004, as a Special Agent investigating white collar fraud. Before working with the USACIDC, I was employed by the Harnett County Sheriff's Office ("HCSO"), Harnett County, North Carolina, from August 2001 to September 2002, where I was assigned as a detective investigating economic crimes and general criminal offenses. Prior to my employment with the HCSO, I worked for the USACIDC, from August 1995 to August 2001, where I investigated economic crimes, general crimes, and drug crimes. During my 23 years of investigative experience, I have dealt with violations of the Uniform Code of Military Justice, the North Carolina General Statues, and Titles 18 and 21 of the United States Code. I also have drafted and served a number of search warrants and arrest warrants authorized by local, state, and federal judges. In my current position with the FDA/OCI, I investigate violations of federal laws including the Federal Food, Drug, and Cosmetic Act ("FDCA"), Title 21, U.S. Code, Sections 301 – 397, and Title 18 of the United States Code. Based on my training and

experience, I am familiar with the rules and regulations governing the drug approval process, methods used to commit fraud against the U.S. Government, and documents and other records that frequently are evidence of such fraud.

During my time as a Special Agent, I have completed specialized training courses at the Department of Homeland Security's Federal Law Enforcement Training Center, the North Carolina Justice Academy, and the USACIDC training facilities. I also have participated in numerous investigations that have resulted in the seizure of evidence, including illegal drugs and documents.

The facts and information contained in this affidavit are based upon my training and experience, participation in investigations, personal knowledge, and observations during the course of this investigation, as well as the observations of other agents involved in this investigation. All observations not personally made by me were relayed to me by the individuals who made them or are based on my review of records, documents, and other physical evidence obtained during the course of this investigation.

This affidavit contains information necessary to support probable cause. It is not intended to include each and every fact and matter observed by me or known to the United States.

RELEVANT FEDERAL LAW

18 USC § 1365, Tampering - Whoever, with reckless disregard for the risk that another person will be placed in danger of death or bodily injury (the term "serious bodily injury" means bodily injury which involves either a substantial risk of death, extreme physical pain, and/or under circumstances manifesting extreme indifference to such risk), tampers with any consumer product that affects interstate or foreign commerce, or the labeling of, or container for, any such product, or attempts to do so.

INTRODUCTION

Based on the information set forth below, your affiant submits that there is probable cause to believe that between August 1, 2017 to January 8, 2018, in the Western District of Virginia, Bryan LEWIS committed the offense of Tampering, when LEWIS knowingly and willingly diverted and tampered with Hydromorphone medication vials intended for the use of patients at various healthcare locations in and around the Roanoke, VA, area.

DETAILS

This investigation was initiated when K. P. and A. T., both from Home Choice Partners, Roanoke, VA, suspected Bryan LEWIS, former pharmacist at Home Choice Partners, of diverting and tampering with vials of hydromorphone from the pharmacy. K.P. originally discovered a needle, alcohol pad, and a bloody tissue in the bathroom toilet of the office. K.P. went around the office and asked the employees if anyone knew anything about the items in the bathroom. When K.P. asked LEWIS about the items, he said that they may have fallen out of his pocket. After contacting human resources, K.P. was told to have every employee administer to a

drug screening. On the day of the drug screening, LEWIS was scheduled off from work, so he was told to come into work for a drug test. A.T. received a phone call later that day from LEWIS. A.T. asked LEWIS if he had taken the drug test, at which time LEWIS explained that it was he who had put the items in the toilet. A.T. asked LEWIS how long the behavior had been going on and LEWIS told her for around nine months. LEWIS then told A.T. that there was a 50ml vial of hydromorphone in the back of the narcotics cabinet that did not contain any hydromorphone, but was replaced with saline.

On February 2, 2018, A.T. gave Diversion Investigator (DI) Jennifer Reed, DEA, Roanoke, VA, three broken vials of Hydromorphone, which LEWIS had claimed broke in-transit to the pharmacy at various points since August 1, 2017. Thompson explained that LEWIS frequently claimed bottles broke in-transit, but suspects LEWIS diverted the liquid controlled substance and then broke the bottles himself to provide an explanation for the missing controlled substances. There were more than these three instances, but only these three bottles were still in the cabinet at the time of the discovery of the diversion and tampering on January 8, 2018. A.T. performed an audit, at which time she noticed that LEWIS would fill a prescription, log the prescription fill on the Controlled Substance Perpetual Inventory log, and then he would go to the computer and void the prescription fill. She also noted where LEWIS received shipments of controlled substances without a witness and she was not sure if he was taking vials of controlled drugs from the hazardous waste container.

On February 2, 2018, K.P. provided DI Reed with copies of all the employee urinalysis tests that the company required the employees on site the day the diversion was discovered.

These test results show that the other ten employees present on January 8, 2018, did not test positive for any illicit substances. It is noted that there is a page with LEWIS ' name, but there are no results listed. DI Reed confirmed with K.P. that the company ordered a test for LEWIS, but LEWIS did not take the test.

K.P. explained that on January 08, 2018, a Pharmacy Technician, E.W. alerted K.P. and A.T. of a needle, alcohol pad and bloody tissue found in a toilet. Inquiries were made of all employees present at the pharmacy. According to A.T., all of the employees were shocked about the found items; however, LEWIS showed no surprise at the mention of what was found and stated it may have fallen out of his pocket.

K.P. stated she had found open needle wrappers in various spots throughout the building (i.e., the freezer and kitchen trash can), and on occasion she found some blood spots in the bathroom. While she thought all those findings were odd, she did not think an employee was diverting and tampering with controlled substances and using them at the office. A.T. provided a list of twenty-three suspect items, either physical incidents or recordkeeping errors, which indicate when LEWIS diverted hydromorphone. One such incident was on October 16, 2017, when another employee, E.W., was drawing hydromorphone out of what was thought to be a new vial and the vial shattered, cutting E.W. on the forearm. E.W. was sent to the Emergency Department and was treated for opioid exposure. D.W., Home Choice employee, had the stopper of a vial of hydromorphone fall into the vial after she inserted a needle into it. A.T. explained to SA Petri that the breaking of the vial and the stopper falling into the other vial were indications of tampering. The broken vial could have occurred as a result of too much liquid being placed

into the vial and the stopper failing. The manufacturer has a set amount of fluids that is placed in the vial, but if liquid is added, this could cause added pressure in the vial and result in the vial breaking. Also, the stopper falling into the vial could have been a result of the stopper being previously punctured multiple times. When the pharmacy employees extract the drug from the vials they do not make multiple punctures in the stopper, because it can loosen the stopper and cause it to fail.

A.T. was on-call the weekend after LEWIS was terminated, January 13, 2018. She received a call from a nurse about a patient experiencing a strange reaction to the medication. A.T. told the nurse that the patient maybe reacting because the contents may be at full strength compared to previous doses received. Thompson thought it may be possible that prior dispenses made by LEWIS were diluted with saline.

On March 8, 2018, INV Amy Tanner, Virginia Department of Health Profession, Roanoke, VA, interviewed LEWIS. LEWIS stated he thought he started using intravenous (IV) hydromorphone around October of 2017. He reported that he began taking the hydromorphone vials discarded in the waste container. He explained that usually, 1ml to 2 ml of drug remained in the vials. After compounding, the used vials would be passed from the cleanroom through the passthrough window. Typically, the vials were "wasted" by tossing the vials into a box located under the cabinet just beneath the passthrough window. Only pharmacists had access to the narcotic lockbox. LEWIS said, he primarily used hydromorphone at night, but after time, he started needing more. When he started to feel withdrawal symptoms, he increased his hydromorphone usage to every 6 to 8 hours a day. LEWIS administered the hydromorphone at

home or in the bathroom while at work. At first, he was using hydromorphone once a week. He said he then started using hydromorphone daily. He said his disease quickly progressed. He started out injecting himself with 0.5 mg of hydromorphone once a day. By January of 2018, he was injecting 10mg to 20mg of hydromorphone every 6 to 8 hours a day. LEWIS said at first it was not hard to divert the hydromorphone from the pharmacy, given the amount of drug left in the vials that were wasted. He said he later had to take whole vials from the narcotics cabinet. He would draw up the hydromorphone into a syringe and then fill the hydromorphone vial with saline. LEWIS said if he did not use hydromorphone that he would experience withdrawal symptoms such as body aches, chills, sweats and shaking. He explained that when he diverted hydromorphone, he would add saline to the vials he removed the hydromorphone vials then he returned the saline-filled hydromorphone vials back to the narcotics cabinet. When asked what other drugs he diverted from the pharmacy, LEWIS said he took any remaining morphine or fentanyl from wasted vials. He could not recall how much or when. He said fentanyl was used infrequently at the pharmacy. He denied diverting any morphine or fentanyl vials from the narcotic cabinet, but he could not recall. LEWIS said hydromorphone was his "drug of choice."

On March 20, 2018, SA Petri and DI Reed interviewed M.B., who stated that he formerly worked at Home Choice Pharmacy from March 2010 to Aug 8, 2017. During his time working at Home Choice, he held several positions to include Branch Manager, Staff Pharmacist, and Pharmacy Manager. The last position that he held was Pharmacy Manager, at which time he was in charge of narcotics, day-to-day operations of the pharmacy, deliveries, staff and other operational tasks. Anytime an employee had to waste a product, the product would have to be placed in a special box for disposal. M.B. described LEWIS as a lazy man, who never

volunteered for anything. In May 2017, LEWIS volunteered to carry the disposal box of the excess waste to the sharps area. The waste is kept in the area until it can be properly disposed of. The waste area is separate from the main pharmacy area and is where they keep extra boxes.

On July 2, 2018, SA Petri received from Cathy Muhlberger, FDA/FCC, the results of the lab examination.

Item 1 consisted of a single, previously opened 50 ml injection vial in a shelf carton with a paper product information insert. The shelf carton was commercially labeled, in part, "Hydromorphone Hydrochloride Injection", "USP, 500 mg/ 50 ml (10 mg/ml)", "50 ml Single-Dose Vial", "Citric Acid 0.2%; Sodium Citrate 0.2%". The injection bottle was missing the crimp ring septum cover and the plastic flip-off cap, which was present on the comparison product vial and appeared to be approximately full of a clear colorless liquid.

Item 1 vial exhibited evidence of tampering. A missing crimp cover plate and a minimum of four punctures on both sides of the vial stopper with at least two different distinct punctures sizes (1 large and 3 small) were observed.

The contents of the suspected tampered bottle (Item 1) and the comparison bottle (Item 8) were as follows:

Item 1 - Hydromorphone HCI - 0.018 (± 0.001) 0.2% of declared product Sodium3 - 3,670 (± 540) Chloride4 - 5,100 (± 1200) Sodium Chloride5 - 0.9% (± 0.2%)

Item 8 - Hydromorphone HCI - 10.4 (± 0.8) 104.3% of declared product Sodium3 - 570 (± 83) Chloride4 - 1,000 (± 200) Sodium Chloride5 – None. Agent's Note: Saline Solution is Sodium Chloride.

On September 19, 2018, SA Petri coordinated this investigation with A.T., who related that the 50ml bottle of Hydromorphone that was in the narcotics cabinet and provided to this office for analysis (See previous lab results) for signs of tampering was maintained with multiple other bottles resembling it. At any given time, there are 50 bottles that are used to create either IV bags or cassettes for their patients. This bottle, like any of the other bottles in the cabinet, could have been used to create a final product for their patients.

On September 19, 2018, A.T. explained to SA Petri that the Hydromorphone used by the pharmacy is manufactured by Akorn Inc., which is produced in Lake Forest, IL and shipped throughout the U.S.

CONCLUSION

Your affiant believes that based on the above described facts and circumstances, and upon your affiant's training, knowledge and experience, your affiant submits there is probable cause to believe that between August 1, 2017 to January 8, 2018, in the Western District of Virginia, LEWIS committed the offense of Tampering, when LEWIS knowingly and willingly diverted and tampered with Hydromorphone in medication vials intended for the use of patients at various healthcare locations in and around the Roanoke, VA, area.

Signed and sworn to this 26 day of September, 2018

Darren C. Petri
Special Agent

Subscribed and sworn to before me this 26th day of September, 2018

The Honorable Pamela Meade Sargent
United States Magistrate Judge